

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Special Nutritionals

ARMS#

12608



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# MEDWATCH

**For VOLUNTARY reporting  
by health professionals of adverse  
events and product problems**

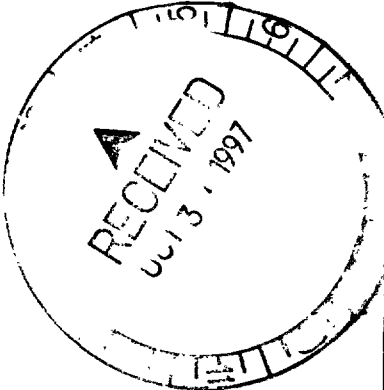
Form Approved- OMB No. 0610-0291 Expires 12/31/96  
See OMB statement at [www.gsa.gov](http://www.gsa.gov)

**FDA use only**

**Trage und  
Sequenzen 2**

only 72196  
12608

Page \_\_\_\_ of \_\_\_\_

A. Patient information			
1. Patient identifier <div style="background-color: black; width: 100px; height: 30px; margin-top: 5px;"></div>	2. Age at time of event: <u>UKN</u>  Date of birth: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight <u>UK</u> lbs or _____ kg
In confidence			
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death _____ (m/d/yyyy) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization		<input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input type="checkbox"/> required intervention to prevent permanent impairment/damage <input checked="" type="checkbox"/> other: _____	
3. Date of event (m/d/yyyy) <u>10/14/97</u>	4. Date of this report <u>10/24/97</u>		
5. Describe event or problem			
THE REPORTER STATED THAT THE PATIENT HAD SEVERE WITHDRAWAL SYMPTOMS AFTER THE DISCONTINUATION OF A SUPPLEMENT CALLED "RIPPED FUEL" GEL CAP. THE PATIENT HAD SIGNS OF DEPRESSION AND CAFFEINE FATIGUE REBOUND.			
			
6. Relevant tests/laboratory data, including dates			
NONE			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
THE PATIENT HAS NO MEDICAL HISTORY. NO KNOWN ALLERGIES.			

<b>C. Suspect medication(s)</b>			
1. Name (give labeled strength & mfr/labeler, if known)			
#1 <b>RIPPED FUEL GEL CAP (TWIN LABS)</b>			
#2			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) <small>(month or best estimate)</small>	
#1 <b>2 TABS 3 X DAY</b>		#1 <b>1 1/2 YEARS</b>	
#2		#2	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 <b>INCREASE ENERGY/STRENGTH</b>		#1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction	
#1 <b>UKN</b>	#1 <b>UKN</b>	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2	#2	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9. NDC # (for product problems only)			
- -			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
<b>TETRACYCLINE</b>			
<b>D. Suspect medical device</b>			
1. Brand name			
2. Type of Device			
3. Manufacturer name & address		4. Operator of device	
<b>REC'D.</b> <b>OCT 27 1997</b>		<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other	
5. Expiration Date <small>(month/year)</small>		6. If implanted, give date <small>(month/year)</small>	
7. If explanted, give date <small>(month/year)</small>		8. If explanted, give date <small>(month/year)</small>	
9. Device available for evaluation? (Do not send to FDA)			
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ <small>(month/year)</small>			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
<b>E Reporter (see confidentiality section on back)</b>			
1. Name & Address		phone #	
2. Health professional?		3. Occupation	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		<b>MD</b>	
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.		4. Also reported to	
<input checked="" type="checkbox"/>		<input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor	

**FDA**

Mail to: **MEDWATCH**  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to:  
1-800-FDA-0178

FDA Form 3500 (1/88)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

# TAKEN BY TELEPHONE

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